UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANA QUINTANA,

Plaintiff,

-against-

B. BRAUN MEDICAL INC.; B. BRAUN INTERVENTIONAL SYSTEMS INC.

Defendants.

17-cv-06614 (ALC)

OPINION AND ORDER GRANTING MOTION TO DISMISS

ANDREW L. CARTER, JR., United States District Judge:

Plaintiff, Ana Quintana ("Plaintiff") brings this action sounding in negligence, strict products liability, breach of warranty, fraud, negligent misrepresentation, and New York consumer protection law against medical device manufacturer B. Braun Medical Inc. and B. Braun Interventional Systems Inc. (collectively, "Defendants"). Plaintiff claims, among other things, that defects in Defendants' inferior vena cava ("IVC") filter, manufactured by Defendants and implanted in her in 2007, have caused her injuries. Defendants now move to dismiss the complaint in its entirety pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that Plaintiff's complaint fails to state a claim upon which relief can be granted. For the reasons that follow, Defendants' motion to dismiss is **GRANTED**.

BACKGROUND

For purposes of this Motion to Dismiss, this court accepts the facts set forth in the Amended Complaint ("Am. Compl.") as true.

A. The Advent of IVC Filters

The inferior vena cava ("IVC") is a vein that returns blood to the heart from the lower extremities. Am. Compl. ¶ 20. In some individuals, blood clots travel from the blood vessels in the leg and pelvis, through the IVC and into the lungs, causing a potentially deadly health

complication called a pulmonary embolism ("PE"). *Id.* These blood clots can also develop in the deep leg veins and are referred to as a deep vein thrombosis ("DVT"). *Id.* The implantation of an IVC filter – a medical device designed to prevent blood clots from travelling to the heart and lungs from the lower extremities – may reduce the risk of DVT or PE in certain high-risk individuals. *Id.* ¶¶ 22-23.

IVC filters were first developed in or around 1967, and were then designed to be permanently implanted in patients. *Id.* ¶ 24. However, concerns over long-term complications with permanent filters led to the development of temporary, retrievable filters beginning in or around 2003. *Id.* ¶ 24. These are designed to be removed when the risk of PE or DVT has passed, *i.e.*, not to remain in the body indefinitely. *Id.* ¶ 25. However, clinical investigations conducted between 2011 and 2015 have revealed that permanent filters are most often retrievable unless there are complications with the device. *Id.* ¶ 54.

B. Defendants' Permanent Filter

Defendants are responsible for the design, manufacturing, packaging, assembling, and distribution of their B. Braun VenaTech™ vena cava filter system (the "Filter"), which is marketed and sold as a permanent device to prevent recurrent pulmonary embolism via placement in the vena cava. *Id.* ¶¶ 5, 26. The Filter is manufactured to be self-centering, with patented stabilized legs intended to prevent the Filter from tilting during implantation to eliminate the possibility of perforation or migration. *Id.* ¶ 27.

In 2001, Defendants obtained FDA clearance to market the Filter under Section 510(k) of the Medical Device Amendment and therefore bypassed the requirement to have the Filter independently evaluated by the FDA or its experts. *Id.* ¶¶ 29-31. The Filter is made of Phynox

wires, a cobalt-chromium-nickel alloy. *Id.* ¶ 38. On or about October 30 2007, the U.S. Food and Drug Administration issued a Class II Device recall on the Filter due to faulty packaging and issues with device sterility and safety. *Id.* ¶ 39. The recall was lifted on March 2, 2008. *Id.*[1] From approximately 2007 to 2013, the FDA released numerous "MAUDE Adverse Event Reports" concerning the Filter, which specified the following incidents: the Filter dislodging in a patient's right ventricle, the legs of the Filter failing to properly deploy, the Filter's arms being bent and misaligned, and a filter migrating to a patient's heart. Am. Compl. ¶¶ 40-43. In 2010 and 2014, the FDA issued alerts to physicians about the risks of permanent and retrievable filters, warning of the risks of leaving IVC filters implanted in patients for extended periods due to their potential to cause adverse health complications. *Id.* ¶¶ 46, 48, 50.

Despite these warnings, Defendants have continued to market the Filter for long-term use. *Id.* ¶ 53. Specifically, Defendants have advertised the construction of the Filter as: "Extraordinary design for exceptional performance. The VenaTech® LP is the new standard in permanent vena caval filtration. . ." *Id.* ¶¶ 78, 84. Defendants have also promoted the Filter as intended "for the prevention of recurrent pulmonary embolism via placement in the vena cava." *Id.* ¶ 85. Defendants further promote the construction of the Filter as "effective [for] clot trapping and preservation of caval patency." *Id.* ¶ 83.

C. Facts of This Case

On or about May 31, 2007, Plaintiff was implanted with the Filter. *Id.* ¶ 61. Prior to implantation, Plaintiff was hospitalized at Bellevue Hospital Center's Radiology Department for

[1] The Court derives some of these facts from the websites cited in Plaintiff's complaint, as a court may consider the contents of a website that Plaintiff's complaint expressly incorporates by reference. *See, e.g., Orozco v. Fresh Direct, LLC*, No. 15-CV-8226 (VEC), 2016 WL 5416510, at *1 (S.D.N.Y. Sept. 27, 2016) (surveying cases).

pulmonary embolism ("PE") and extensive deep vein thrombosis ("DVT") in her left lower extremities. *Id.* ¶¶ 61, 63. Plaintiff also had a history of hypertension prior to surgery. *Id.* ¶ 62. Plaintiff underwent surgical implantation of Defendants' Filter to prevent further DVT and pulmonary embolism. *Id.* ¶ 62. Dr. Richard Lefleur conducted the surgery. *Id.* ¶ 65. The Filter implanted into Plaintiff was positively identified as Defendants' Filter and was implanted and utilized in accordance with Defendants' Instructions for Use ("IFU"). *Id.* ¶¶ 66-67, 146.[2] Plaintiff was never considered for revision or removal of the device by any medical professional. *Id.* ¶ 68.

On October 30, 2014, Plaintiff was hospitalized for a large cerebellar stroke, which was evaluated by Dr. Eric Leibert at Bellevue Hospital Center in New York. *Id.* ¶ 69. Plaintiff was diagnosed with having a PE and "inf[ra]ction post IVC filter insertion." *Id.* ¶ 70. According to Plaintiff, PE is a complication of DVT, and "IVC filters have been shown to increase rate[s] of DVTs." *Id.* ¶ 71. The Filter remains in her body to date. *Id.* ¶ 75.

Plaintiff claims that the Filter has "a design defect causing the Filter to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo." *Id.* ¶ 86. As a result, Plaintiff has suffered health complications, namely her stroke and PE, emotional distress, and the psychological trauma of living with a defective product implanted in her body. *Id.* ¶¶ 76, 91.

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[2] Plaintiff has appended the IFU to its papers in opposition to Defendants' Motion to Dismiss. Because Plaintiff relies upon this document in her complaint, the Court may validly consider the IFU in adjudicating this motion. *See McLennon v. City of New York*, 171 F. Supp. 3d 69, 88 (E.D.N.Y. 2016) ("To be incorporated by reference, the complaint must make a clear, definite and substantial reference to the documents.") (quoting *Madu, Edozie & Madu, P.C. v. SocketWorks Ltd. Nigeria*, 265 F.R.D. 106, 123 (S.D.N.Y. 2010)).

D. Procedural History

Plaintiff filed her complaint on August 30, 2017. *See* Complaint (ECF No. 1). On September 1, 2017, Defendants filed a letter requesting a pre-motion conference in anticipation of their filing a motion to dismiss. *See* Letter dated September 1, 2017 (ECF No. 6). The Court held a pre-motion conference on October 5, 2017. Plaintiff was given an opportunity to amend her complaint, which we she proceeded to do on October 19, 2017. *See* Am. Compl. (ECF No. 10). Briefing on the instant motion then followed.

STANDARD OF REVIEW

When deciding a motion to dismiss the Court "must accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." *LaFaro v. N.Y. Cardiothoracic Grp., PLLC*, 570 F.3d 471, 475 (2d Cir. 2009) (internal quotation marks omitted). The Court will not dismiss any claims pursuant to Rule 12(b)(6) unless the plaintiff has failed to plead sufficient facts to state a facially plausible claim to relief. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). To state a plausible claim, plaintiff must provide "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged"—a standard that requires "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). However the court need not credit "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Iqbal*, 556 US at 678 (citing *Twombly*, 550 U.S. at 555). Instead, the complaint must provide factual allegations sufficient "to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Port Dock & Stone Corp. v. Oldcastle Ne., Inc.*, 507 F.3d 117, 121 (2d Cir. 2007) (citing *Twombly*, 550 U.S. at 555). "[W]here the well-pleaded facts do

not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not shown—that the pleader is entitled to relief." *Iqbal*, 556 U.S. at 679 (internal quotation marks omitted); *see* Fed. R. Civ. P. 8(a)(2).

DISCUSSION

Plaintiff asserts eight causes of action in her amended complaint. The first four causes of action – 1) negligence; 2) strict liability: failure to warn; 3) strict liability: design defect; 4) breach of express warranty – are contingent upon Plaintiff plausibly alleging a defect. Plaintiff's remaining causes of action – 5) fraudulent misrepresentation; 6) fraudulent concealment; 7) negligent misrepresentation; and 8) consumer fraud, pursuant to N.Y. Gen. Bus. Law §§ 349, 350 – are all premised on fraud committed by Defendants. Each group of claims is addressed in turn.

I. Claims Pertaining to Product Defect

Under New York law, Plaintiff's claims sounding in negligence and strict liability are functionally equivalent and analyzed here together. *See, e.g.*, *Searle v. Suburban Propane Div. of Quantum Chem. Corp.*, 700 N.Y.S.2d 588, 591 (N.Y. App. Div. 3d Dep't 2000) ("[I]n a design defect case, there is almost no difference between a prima facie case in negligence and one in strict liability."); *Estrada v. Berkel Inc.*, 789 N.Y.S.2d 172, 173 (N.Y. App. Div. 2d Dep't 2005) ("Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent[.]") (citation omitted). State law "provides four theories upon which a claim of products liability may be founded: (1) express warranty; (2) implied warranty; (3) negligence; and (4) strict liability." *Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 252 (E.D.N.Y. 2014) (citing *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983)). To recover under any of these four theories, a plaintiff must demonstrate "that the product at issue was

defective, and that the defectively designed product was the actual and proximate cause of the plaintiff's injury." *Id.* (citing *Voss*, 450 N.E.2d at 208-09). There are three iterations of product defects under New York law: (1) design defects; (2) manufacturing defects; and (3) defective or inadequate warnings." *Id.* (citing *Voss*, 450 N.E.2d at 207). Here, Plaintiff bases her claims on design defects and failure to warn.

A. Design Defect

Under New York law, a plaintiff establishes a prima facie case of products liability for a design defect by showing: (1) that the product, as designed, posed a substantial likelihood of harm; (2) that it was feasible for the manufacturer to design the product in a safer manner; and (3) that the defective design was a substantial factor in causing plaintiff's injury. *Am. Guarnatee & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09-CV-8357 (BSJ) (HBP), 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010); *see Cover v. Cohen*, 461 N.E.2d 864, 866 (N.Y. 1984).

Here, Plaintiff has, at the least, failed to adequately allege that the product was defective and that any defect was a substantial factor in causing her injuries. Notably absent from Plaintiff's complaint is an allegation of a specific defect or any facts about the "circumstances of the purported failure" of the Filter that would give rise to the inference of proximate cause. *Parillo v. Stryker Corp.*, No. 15-CV-155 (BKS) (RFT), 2015 WL 12748006, at *3 (N.D.N.Y. Sept. 29, 2015). Plaintiff's only attempt to identify a specific defect is a boilerplate reference to "a design defect causing the Filter to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo." Am. Compl. ¶ 86;[3] *see id.* ¶ 97 (stating that the Filter was

[3] A Westlaw search of this phrase, or variations thereof, yields dozens of results, including, far most predominantly, complaints filed throughout the country in medical device defect cases. However, nearly all of those complaints include not only this phrase but a significantly more detailed exposition of the specific defect or diagnosis.

designed so as to present an unreasonable risk of fracture, migration, and tilting of the Filter due to "insufficient strength or structural integrity of the device to withstand normal placement within in the human body").

Of course, identifying a specific defect is not strictly necessary if Plaintiff can "prove that the product did not perform as intended and exclude all other causes for the product's failure that are not attributable to defendants[.]". *Parillo*, 2015 WL 12748006, at *3 (citation omitted). In *Parillo,* the court opined that requiring a Plaintiff to allege a specific defect where technical and scientific knowledge is involved may "contravene the notice pleading requirement." *Id.* The *Parillo* court found that the plaintiff sufficiently pled his negligence claim by alleging facts "based on the circumstances of the purported failure of the Gamma 3 Hip Fracture System." *Id.* Specifically the plaintiff pled a "hardware failure," and that "a product defect was determined to be the cause of the hardware failure." *Id.*; *see Williamson v. Stryker Corp.*, No. 12-CV-7083 (CM), 2013 WL 3833081, at *5 (S.D.N.Y. July 23, 2013) (finding that plaintiffs sufficiently alleged facts of a defect by alleging that the knee device broke and presenting X-rays taken at the time of both breaks, which revealed a "total mechanical failure.").

Plaintiff's complaint here, however, is devoid of any facts that explain the cause of her stroke or her diagnosis. Plaintiff's theory of causation is as follows: Plaintiff was initially hospitalized for PE and DVT and implanted with Defendants' Filter. Am. Compl. ¶¶ 61-62. The Filter was properly implanted and utilized per the Defendants' instructions. *Id.* ¶ 67. Years later, Plaintiff was hospitalized for a cerebellar stroke and "diagnosed with having a pulmonary embolism and inf[ra]ction post IVC filter insertion." *Id.* ¶¶ 69-70. As such, the Filter must have been defective. Plaintiff further suggests that the device was defective because it presented risks

of fracture, migration, and titling, but does not state any facts to indicate how those risks resulted from a specific design defect, or how that defect was a substantial factor in causing *her* injuries.

In that regard, Plaintiff's reliance upon the assumption that her device must have failed because of reports of failures or complications by other consumers is plainly inadequate. *See, e.g.*, *Oden v. Boston Sci. Corp.*, No. CV180334SJFSIL, 2018 WL 3102534, at *4 (E.D.N.Y. June 4, 2018) (dismissing design defect and negligence claim premised upon design defect claim because "[Plaintiff's] list of allegedly unreasonable risks posed by [Defendants' IVC Filter's] purportedly defective design does not identify a specific component or particularized issue with the design itself. Similarly, Plaintiff's allegation that [Defendants' IVC] Filter was 'defective in design ... because when it left the hands of Defendant, the product was unreasonably dangerous,' lacks any facts indicating the particular component that was defective or otherwise identifying a specific problem with [Defendants' IVC] Filter that caused it to be unreasonably dangerous." (internal citations omitted)).

In *Rodman v. Stryker Sales Corporation*, 604 F. App'x 81 (2d Cir. 2015), the Court of Appeals upheld a district court's dismissal of an amended complaint that alleged the plaintiff's hip implant was defective because of improper workmanship and the application of the Hydroxyapatite coating. *Id.* at 82. The Court held that the plaintiff failed to state a claim because "he never identified how this problem rendered the product defective, whether it affected his individual hip replacement, or how it caused his alleged injuries." *Id.* Plaintiff's amended complaint suffers from the same, and arguably more glaring, deficiencies; it does not identify an actual defect in the device (even in the abstract), and says nothing about how the device's

"inf[ra]ction"[4] caused Plaintiff's injuries. For these reasons, her design defect claim must be dismissed.

Plaintiff appears to suggest in the alternative that, because she has pleaded *res ipsa loquitur*, she should be subject to less stringent causation requirement. Plaintiff's Amended Memorandum of Law in Opposition to Motion to Dismiss the Complaint at 6 (ECF No. 27). However, as then-District Judge Sonia Sotomayor has explained, *res ipsa loquitur* is an evidentiary principle and "does not apply to pleading requirements." *Chauvet v. Local 1199, Drug, Hosp. & Health Care Employees Union*, No. 96-CV-2934 (SS), 1996 WL 665610, at *18 (S.D.N.Y. Nov. 18, 1996). And, even if *res ipsa loquitur* could suffice for pleading purposes, Plaintiff fails to provide sufficient factual exposition to account for the possibility that other factors caused her injury. *See Lindenauer v. State*, 356 N.Y.S.2d 366, 368 (N.Y. App. Div. 3d Dep't 1974) (finding that because claimant failed to trace the journey of the exploding container from the bottler to her hands to warrant inference that the State, rather than another, was responsible for her injuries *res ipsa loquitur* was improperly applied); *see also, e.g.*, *Flagg v. Elliot*, No. CIV.A. 14-0852, 2014 WL 3715127, at *6 (E.D. La. June 16, 2014) (suggesting that pleading *res ipsa loquitur* alone does not satisfy pleading requirement, especially where Plaintiff has not provided sufficient factual allegations to rule out other causes).

Ignoring conclusory assertions and the recitation of legal standards, Plaintiff fails to allege any facts that plausibly establish a defect or causation.[5] For the reasons set forth above, the Court

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[4] Plaintiff's amended complaint is unclear as to the nature of the "inf[ra]ction," as well as whether Defendant's device was the subject of that infraction. *See* Am. Compl. ¶ 70.

[5] It also appears that Plaintiff's design defect claim fails for failure to allege a feasible design alternative. Some courts have disagreed about whether a plaintiff must plead a feasible design alternative in light of the technical knowledge that may be required. *Compare Guarascio v. Drake Assocs. Inc.*, 582 F. Supp. 2d 459, 463 (S.D.N.Y. 2008) (suggesting how "competent, non-conclusory expert testimony is needed in cases involving more complex

concludes that Plaintiff's design defect claims, whether pursued under negligence or strict liability, must be dismissed.

B. Failure to Warn

Plaintiff also alleges that Defendants failed to accompany the Filter with adequate warnings and instructions. Am. Compl. ¶ 97. In order to recover under a failure to warn theory, a claimant must show: "(1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm." *Am. Guarnatee*, 2010 WL 5480775, at *3 (quoting *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 84 (S.D.N.Y. 2001)). As part of satisfying those elements, a plaintiff is "required to prove that the product did not contain adequate warnings." *Mulhall v. Hannafin*, 841 N.Y.S.2d 282, 285 (N.Y. App. Div. 1st Dep't 2007). Generally, whether a warning is adequate is an issue of fact to be determined at trial. *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003) (quoting *Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991)). "There are several important considerations that directly affect the adequacy of a warning, including the location and conspicuousness of the warning and the method in which the warning is communicated to the ultimate user." *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 440 (S.D.N.Y. 1999).

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design issues" to demonstrate design alternative at summary judgment), *and Parillo*, 2015 WL 12748006, at *6 (surveying cases before concluding that requiring a plaintiff to allege alternative safer design would require expert testimony inappropriate for pleadings stage), *with Tuosto v. Philip Morris USA Inc.*, No. 05-CV-9384 (PKL), 2007 WL 2398507, at *12 (S.D.N.Y. Aug. 21, 2007) (suggesting expert testimony regarding feasible alternative design is necessary at pleading stage), *and Oden*, 2018 WL 3102534, at *4 (dismissing complaint on this basis). However, assuming such a requirement is appropriate, it is clear that a retrievable filter, the only alternative design Plaintiff alleges, is not an appropriate comparator. *Id.* (dismissing complaint on alternative ground that Plaintiff failed to identify feasible alternative designs, and rejecting argument that retrievable filter would have been viable alternative because it is different from a permanent filter).

Here, Plaintiff's allegations of inadequate warnings of which Plaintiff complains are, for the most part, conclusory. *See, e.g.*, Am. Compl. ¶ 87 ("Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the B. BRAUN VenaTech™ vena cava filter."). Although Plaintiff vaguely discusses aspects of Defendants' brochure and IFU that she claims were deficient, *id.* ¶¶ 143, 146-48, she fails to identify *how* those warnings were inadequate. *Oden*, 2018 WL 3102534, at *6-*7 (dismissing complaint containing nearly identical language on same basis) (citing, *inter alia*, *Parillo*, 2015 WL 12748006, at *7).

However, Plaintiff's failure to warn claim fails for the wholly separate reason that, like her design defect claim, she has not plausibly pled causation. "To constitute proximate cause, an inadequate warning must be a substantial cause of the events leading to the injury. An act cannot be the 'substantial cause' if the injury would have occurred regardless of the content of defendant's warning." *Figueroa*, 254 F. Supp. 2d at 370. That said, New York courts have recognized "that causation may sometimes be inferred from the facts and circumstances that the plaintiff has presented and has applied this principle in the context of determining whether a failure to warn was the proximate cause of an accident, i.e., whether a warning would have been heeded." *Raney v. Owens-Illinois, Inc.*, 897 F.2d 94, 96 (2d Cir. 1990).

To this point, Plaintiff alleges, "as a direct and proximate cause of the wrongful acts and omissions of Defendants, Plaintiff suffered economic damages, severe injuries, and emotional distress." *See* Am. Compl. ¶ 156. This conclusion, however, is not sufficient to plausibly show that the failure to warn Plaintiff's physician caused Plaintiff's injuries because we know nothing about what caused her stroke – *i.e.*, what about the device failed or what was Plaintiff's diagnosis

– nor anything about whether Plaintiff would have heeded an appropriate warning. *See Molina*, 199 F. Supp. 2d at 93 ("Under New York law, a claimant must adduce evidence showing that a failure to warn was a substantial factor in causing [plaintiff's] injury." (internal quotation marks and citation omitted)). For these reasons, Plaintiff's negligence and strict liability claims, as based upon a failure to warn theory, are dismissed.

C. Express Warranty

An express warranty is formed by "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods" or "any description of the goods" that is "part of the basis of the bargain." *Williamson*, 2013 WL 3833081, at *8 (quoting N.Y. U.C.C. § 2–313). While it is not required to use formal words such as "warrant" or "guarantee," nor allege that the speaker had a specific intention to make a warranty, "an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." *Id.* "To establish the breach of an express warranty, the plaintiff must show that there was an 'affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase' and that the warranty was relied upon to the plaintiff's detriment." *Goldin v. Smith & Nephew, Inc.*, No. 12-CV-9217 (JPO), 2013 WL 1759575, at *6 (S.D.N.Y. Apr. 24, 2013) (citing *Barrett v. Black & Decker (U.S.) Inc.*, No. 06-CV-1970 (SCR) (MDF), 2008 WL 5170200, at *12 (S.D.N.Y. Dec. 9, 2008)). As alluded to above, "a successful breach of warranty claim requires that the product be defective." *Plemmons v. Steelcase Inc.*, No. 04-CV-4023 (LAP), 2007 WL 950137, at *5 (S.D.N.Y. March 29, 2007).

The Amended Complaint alleges that Defendants "expressly warranted that [the Filters] were safe and effective, and fit for the uses for which they were designed, marketed, manufactured

and distributed." Am. Compl. ¶ 175. Moreover, Plaintiff argues that Defendants' website also contained numerous representations that the Filter was "safe, effective and fit for implantation into the IVC to prevent PE and DVT." *Id.* ¶ 164. Plaintiff cites Defendants' website for the proposition that the website made various explicit warranties, specifically that the Filter was "extraordinar[ily] design[ed] for exceptional performance ... setting the new standard for permanent vena caval filtration," *id.* ¶¶ 165-170., from which "plaintiff through her physicians . . . did rely on." *Id.* ¶ 177; *see id.* ¶ 202 (suggesting that Defendants made such warranty at time of sale of filter to Plaintiff).

Even assuming that these vague statements regarding product safety and performance sufficed to amount to a warranty, *Williamson*, 2013 WL 3833081, at *9, Plaintiff has failed to adequately plead reliance because her amended complaint lacks details regarding whether and how Plaintiff or her physicians reviewed and relied upon these warranties. *Oden*, 2018 WL 3102534, at *8 (dismissing warranty claim on basis of similar, insufficient language supporting reliance) (citations omitted). In addition, for the reasons set forth above, *supra*, Section I.A, Plaintiff has failed to adequately allege that her product was defective. *See Goldin*, 2013 WL 1759575, at *6 ("Plaintiff has not alleged with sufficient specificity the requisite representation by [defendants], nor has Plaintiff alleged sufficient facts in support of her allegation that the [product] was, in fact, defective").

Accordingly, Plaintiff's breach of express warranty claim is dismissed, and it is unnecessary to reach Defendants' alternative arguments.

II. Fraud-Based Claims

A. Fraudulent Misrepresentation and Fraudulent Concealment

To state a claim for fraudulent misrepresentation under New York law, a plaintiff must show: "(1) the defendant made a material false representation, (2) the defendant intended to defraud the plaintiffs thereby, (3) the plaintiffs reasonably relied upon the representation, and (4) the plaintiffs suffered damage as a result of their reliance." *Swersky v. Dreyer & Traub*, 643 N.Y.S.2d 33, 36 (N.Y. App. Div. 1st Dep't 1996). A claim for fraudulent concealment requires the same showing as that for fraudulent misrepresentation, with the additional requirement that the plaintiff must demonstrate that the defendant had a duty to disclose material information. *See Banque Arabe et Internationale D'Investissement v. Md. Nat. Bank*, 57 F.3d 146, 153 (2d Cir. 1995); *Manhattan Motorcars, Inc. v. Automobili Lamborghini, S.p.A.*, 244 F.R.D. 204, 213 (S.D.N.Y. 2007). For both forms of fraud, the element of damage includes a requirement that the plaintiff establish proximate causation. *In re Fosamax Prod. Liab. Litig.*, 924 F. Supp. 2d 477, 489 (S.D.N.Y. 2013); *see, e.g.*, *Hunt v. Enzo Biochem, Inc.*, 471 F. Supp. 2d 390, 399–400 (S.D.N.Y. 2006) (stating that a claim of common law fraud under New York law "requires a showing of proximate causation").

Fraudulent Misrepresentation and Fraudulent Concealment are subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b), which provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *Warren v. John Wiley & Sons, Inc.*, 952 F. Supp. 2d 610, 621 (S.D.N.Y. 2013) ("[L]ike a claim for fraud, a claim of fraudulent concealment must be [pleaded] with particularity, in accordance with the heightened pleading standards of Fed. R. Civ. P. 9(b)."

(internal citations and quotation marks omitted)). To comply with Rule 9(b), a complaint alleging fraudulent misrepresentation under New York law must: "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006) (quoting *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993)). "A statement is 'fraudulent' if it was falsely made, or caused to be made, with the intent to deceive." *United States v. Sabbeth*, 262 F.3d 207, 217 (2d Cir. 2001) (citations omitted). Furthermore, where the fraudulent inducement claim is premised on concealment so that the plaintiff cannot specify the time and place because no affirmative act occurred, the complaint must still specify: "(1) what the omissions were; (2) the person responsible for the failure to disclose; (3) the context of the omissions and the manner in which they misled the plaintiff, and (4) what defendant obtained through the fraud." *Abbatiello*, 522 F. Supp. 2d at 533–34 (quoting *Malmsteen v. Berdon, LLP*, 477 F. Supp. 2d 655, 664–65 (S.D.N.Y. 2007)).

Plaintiff alleges that Defendants fraudulently concealed and omitted eleven pieces of information from their webpage which hosted the Filter's Product Brochure. *See* Am. Compl. ¶¶ 191-197, 202, 204. Putting aside conclusory allegations, Plaintiff claims, in essence, that Defendants misrepresented the product as safe without disclosing the full breadth of the known risks of the Filter, and that Defendants omitted that the Filter was defective and could cause dangerous side effects. *Id.* Plaintiff also alleges that the representations and omissions in the product brochure are similar to those in the brochure given to Plaintiff's healthcare provider and "possibly" to Plaintiff before implantation of the Filter. *Id.* ¶¶ 192, 225. Plaintiff's allegations with respect to the representations in the product brochure recite the specific words used. *See id.*

¶¶ 202, 227.

As an initial matter, Plaintiff's allegations premised upon affirmative misrepresentations fail to sufficiently "identify the speaker, state where and when the statements were made (or were viewed), and explain why the statements were fraudulent." *Oden*, 2018 WL 3102534, at *10 (dismissing fraud allegations based on similar allegations of misstatements and omissions derived from IVC filter manufacturer's website and brochure) (internal quotation marks and citations omitted); *Perez v. B. Braun Medical, Inc.*, No. 17-CV-8512 (LLS), 2018 WL 2316334, at *6 (S.D.N.Y. May 9, 2018) (dismissing fraud claim based on nearly identical allegations on the basis that Plaintiff failed to explain why statements were fraudulent). Similarly, Plaintiff's allegations based upon fraudulent concealment are similarly vague and fail to specifically set forth the omitted information, who was responsible for those omissions, the specific context of the omissions, and what Defendants obtained through concealing those matters. *See* Am. Compl. ¶ 204 (setting forth a list of intentionally omitted matters, but in vague terms); *Oden*, 2018 WL 3102543, at *12 (dismissing fraudulent concealment claim for "substantive lack of detail as to the exact nature of the alleged omissions, the individual or individuals responsible for the omissions, the context of the omission and what Defendants obtained through the alleged fraud" based upon similarly worded list); *Perez*, 2018 WL 2316334, at *6 (same, because Plaintiff's complaint "assume[d] that there are complications and injuries of which defendants failed to warn her, but not what they are.").

In addition, Plaintiff has failed to allege sufficient facts to establish an intent to deceive. Because Plaintiff fails to explain why the alleged statements are fraudulent, and does not plausibly allege a defect or otherwise how the device failed to perform as Defendants promised, Plaintiff

cannot establish fraudulent intent. Notably, the wealth of the warnings cited by Plaintiff occurred well after her device's implantation. *Perez*, 2018 WL 2316334, at *6 (dismissing fraud claim based on nearly identical allegations on the alternative basis that Plaintiff failed to demonstrate why they were made with an intent to deceive).

Even were that not the case, while the Amended Complaint also states that Plaintiff and her physicians reasonably relied on those representations (Am. Compl. ¶¶ 212-213), and that Defendants knew recipients of these representations would rely and take action based upon this information (*id.* ¶ 206), these allegations are merely conclusory, especially without any factual allegations indicating when Plaintiff or her physician viewed the Product Brochure, or that they even actually read or viewed the Product Brochure. *See Oden,* 2018 WL 3102534, at *11 (dismissing fraud claim based on nearly identical language on this alternative basis); *Sullivan v. Aventis, Inc.*, No. 14-CV-2939 (NSR), 2015 WL 4879112, at *9 (S.D.N.Y. Aug. 13, 2015) (dismissing Plaintiff's fraud claim because she did not specifically allege that her mother read or view the fraudulent representations).

For these reasons, both the fraudulent inducement and fraudulent concealment claims are dismissed.

B. Negligent Misrepresentation

To state a claim for negligent misrepresentation, a plaintiff must show that: (1) the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that he or she should have known was incorrect; (3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff

reasonably relied on it to his or her detriment. *Eaves v. Designs for Fin., Inc.*, 785 F. Supp. 2d 229, 254 (S.D.N.Y. 2011) (quoting *Hydro Investors, Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 20 (2d Cir. 2000)).

Defendants argue, relying on *Eaves*, that where, as here, the negligent misrepresentation claim is based on the same set of facts as those upon which a fraud claim is grounded, Rule 9(b) applies to the negligent misrepresentation claim as well. 785 F. Supp. 2d at 254–55. However, "[t]he Second Circuit has stated that Rule 9(b) may or may not apply to state law claims for negligent misrepresentation." *Fisher v. APP Pharm., LLC*, 783 F. Supp. 2d 424, 432 (S.D.N.Y. 2011) (quoting *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y.*, 375 F.3d 168, 188 (2d Cir. 2004)). In the present case, the Court does not need to resolve the issue, because even under the more lenient standards of Rule 8(a), Plaintiff's negligent misrepresentation fails because she has not plausibly alleged reliance.

"A plaintiff alleging negligent misrepresentation must establish reliance upon a false statement or material misrepresentation or omission, and the learned intermediary rule eliminates the possibility of any such reliance." *Amos v. Biogen Idec Inc.*, 249 F. Supp. 3d 690, 697 (W.D.N.Y. 2017) (internal citations and quotations marks omitted).[6] Plaintiff alleges that she was told the Filter was a better option than putting her on medication and based on that advice decided to have the Filter implanted. Am. Compl. ¶¶ 63-64. However, this allegation indicates only that Plaintiff relied on her physician's advice and leaves open the question whether the

[6] The "learned intermediary rule" provides that "[w]arnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects, and the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." *Id.* (citing *Martin v. Hacker*, 628 N.E.2d 1308 (N.Y. 1993)).

physician relied on Defendants' representations when giving Plaintiff that advice. Because Plaintiff fails to plausibly allege what misrepresentation her physician relied on, her negligent misrepresentation claim is dismissed. *See Glidepath Holding B.V. v. Spherion Corp.*, 590 F. Supp. 2d 435, 459 (S.D.N.Y. 2007) ("[W]hether a plaintiff has adequately pleaded justifiable reliance can be a proper subject for a motion to dismiss in certain circumstances.").

C. Consumer Fraud Under the General Business Law

Section 349 of New York General Business Law makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law. § 349(a). Section 350 prohibits "[f]alse advertising in the conduct of any business." N.Y. Gen. Bus. Law § 350. To state a claim for deceptive practices under either section, a plaintiff must show: (1) that the act, practice or advertisement was consumer-oriented; (2) that the act, practice or advertisement was misleading in a material respect, and (3) that the plaintiff was injured as a result of the deceptive practice, act or advertisement. *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 524–25 (S.D.N.Y. 2003). To state a claim under the statute, a plaintiff must, "as a threshold matter, ... charge conduct of the defendant that is consumer-oriented," *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 647 N.E.2d 741, 744 (N.Y. 1995), defined as conduct that "potentially affect[s] similarly situated consumers." *Id.* at 745. Consumer-oriented conduct does not require a repetition or pattern of deceptive conduct, but a plaintiff must nevertheless "demonstrate that the acts or practices have a broader impact on consumers at large." *Id.* at 744. In addition, "[t]o properly allege causation, a plaintiff must state in his complaint that he has seen the misleading statements of which he complains before he came into possession of the products he purchased." *Goldemberg v. Johnson*

& Johnson Consumer Cos., Inc., 8 F. Supp. 3d 467, 480 (S.D.N.Y. 2014) (citing, *inter alia*, *Gale v. Int'l Bus. Machs. Corp.*, 781 N.Y.S.2d 45 (N.Y. App. Div. 2d Dep't 2004)).

Here, Defendants argue that Plaintiff's General Business Law claims fail for insufficiently specifying the precise misrepresentation and how those misrepresentations were material. Defendants' Memorandum of Law in Support of Motion to Dismiss the Complaint ("Defs' Mem.") at 19 (ECF No. 20). Defendants alternatively contend that Plaintiff's consumer protection claims are precluded under the learned intermediary rule. Defs' Mem. at 20.

Plaintiff fails to allege sufficient facts to support violations of sections 349 and 350 of the General Business Law. Plaintiff merely alleges that: (1) Defendants represented on their website and in their brochure that the Filter was safe for its intended uses but knew it was defective; (2) they knew the falsity of their representations about the Filter's safety, which Plaintiff and her physician justifiably relied upon to her detriment; and (3) Defendants' misrepresentations proximately caused her injuries. Beyond these assertions and conclusory statements, Plaintiff advances no other allegations regarding how Defendants' alleged deceptive or misleading business practices harmed her. *See Stadt v. Fox News Network LLC*, 719 F. Supp. 2d 312, 324 (S.D.N.Y. 2010) (finding no Gen. Bus. Law § 349 violation where the complaint lacked allegations that the defendant "harmed consumers or the public interest in any material respect" (footnote omitted)). These allegations do not suggest Plaintiff ever saw these statements and under what circumstances. *Oden*, 2018 WL 3102534, at *14 (dismissing claim under sections 349 and 350 based on similar allegations because Plaintiff failed to adequately allege having relied on certain misstatements in product brochure and website) (citation omitted). Thus, even assuming that Plaintiff has

adequately alleged the first two elements of her General Business Law claim,[7] she has not adequately pled causation.

As such, Plaintiff's claims arising out of the General Business law are dismissed.

III. Punitive Damages

In light of the Court's dismissal of Plaintiff's other claims, it is unnecessary for the Court to reach Defendants' remaining contentions regarding dismissal of Plaintiff's prayer for punitive damages, which is not a self-sustaining claim. *ACR Sys., Inc. v. Woori Bank*, 232 F. Supp. 3d 471, 479 (S.D.N.Y. 2017) (citing *Martin v. Dickson*, 100 F. App'x 14, 16 (2d Cir. 2004)).

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is **GRANTED** and the amended complaint is dismissed. The Clerk of Court is respectfully directed to terminate all pending motions and close this case.

SO ORDERED.

Dated: July 24, 2018
New York, New York

ANDREW L. CARTER, JR.
United States District Judge

[7] This itself is a questionable proposition. *See Perez*, 2018 WL 2316334, at *6 (dismissing claim under sections 349 and 350 based upon similar allegations for failure to demonstrate materially misleading representations because the fact that "there are side effects associated with IVC filters that are implanted long-term, does not mean that [Plaintiff's] IVC filter has not been effective for implantation into the IVC to prevent PE and DVT for which it was designed or that it is not safer than the alternative").